UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/894,767	02/23/98	WEITSCHIES W	SCH1526

023599 HM12/0511
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EXAMINER	
DO, P	
ART UNIT	**PAPER NUMBER**
1641	16

DATE MAILED: 05/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/894,767	Weltschles et al.
Examiner	**Art Unit**
Pensee T. D	1641

-- The MAILING DATE of this communication appears on the cover sh et with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 2, 2001*

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-18, 22-32, and 35-39* is/are pending in the applica

4a) Of the above, claim(s) *3, 6, 7, 26-32, and 35-38* is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 2, 4, 5, 8-18, 22-25, and 39* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *3, 6, 7, 26-32, and 35-38* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. The reason for the restriction requirement was properly addressed in the previous office action. The Examiner still maintains the requirement.

2. Regarding the "missing text" on page "1A", the Examiner clarifies that page 1A is the abstract. However, because the page was not labeled as "Abstract" and was placed after the first page of the specification, the examiner was mistaken that it was the second page of the specification.

3. Regarding the arguments concerning the impropriety of the election of species, the examiner has responded to the arguments by issuing a new restriction requirement sent on July 5, 2000.

Withdrawn Rejection(s)

4. Rejections under 35 U.S.C. 112, 2nd paragraph in the previous office action are withdrawn herein due to the amendment filed on February 2, 2001.

5. Rejection under 35 U.S.C. 102(b) by Josephson is withdrawn herein.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 U.S.C. § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 2, 4, 5, 8-18, 22-25, 39 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A separation step is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Claim 1-2 recites a heterogeneous immunoassay but fails to recite a separation step. According to the invention, the measurement of the remanent magnetization takes place right after the addition of the ferromagnetic or ferrimagnetic labels to the sample.

Maintained Rejections

Claim Rejections - 35 U.S.C. § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 4, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 3220442 A (TDK Corp).

TDK Corp. teaches a method of determining the concentration of antigen/antibody in a liquid sample, comprising suspending magnetic fine particles fixed with antibody/antigen binding specifically with the analyte, the antigen/antibody, in a liquid sample containing said analyte to cause agglutination of the magnetic fine particles by antigen-antibody reaction; applying a magnetic field to the suspension liquid containing the agglutinated matter to align the magnetic

fine particles; stopping the magnetic field; and measuring the remanent magnetic flux density of the agglutinated matter to determine the particle size of the agglutinated matter. (See abstract).

10. Claims 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen et al. (EP0180384 July 1986).

Cohen et al. teach a stable magnetically responsive reagent carrier, substantially remanent-free particulate reagent carrier useful in immunoassay procedures. The particulate reagent carrier comprises particles or beads, each formed of a water-insoluble matrix, e.g. a gel, swellable in an aqueous solution having colloidally dispersed therein superparamagnetic granules. The size range of the particles is from 5 to 500 nanometers. The reagent carrier comprises a polymeric matrix, in which the magnetic substance is incorporated, is water insoluble but swellable in aqueous medium. (See pages 4-6).

Claim Rejections - 35 U.S.C. § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 3220442 (TDK, Corp.) further in view of Cohen et al.

TDK, Corp. has been discussed above.

However, TDK, Corp. does not teach the particle size range from 1-1000 nm or the ferromagnetic and ferrimagnetic substances are stabilized with a shell that is made of oligomeric or polymeric carbohydrates, proteins, peptides, nucleotides, surfactants, synthetic polymers and/or lipids.

Cohen et al. teach the particle size range from 5-500 nm and a polymeric matrix.

It would have been obvious to one of ordinary skill in the art to use particles of size range taught by Cohen et al. in the method of TDK, Corp. because such size range falls within the size range of colloidal particles.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

14. Claims 1, 9, 10, 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 15, 20 of U.S. Patent No. 6,027,946. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both the pending application and Patent '946 are drawn to a method for

qualitative/quantitative detection of analytes in liquid phase or solid phase, comprising labeling the analytes with stable ferromagnetic colloidal particles or ferrimagnetic colloidal particles and determining the magnetization of the labeled analytes as a quantitative or quantitative measurement of the analyte.

Response to Arguments

15. Applicant's arguments filed February 21, 2001 have been fully considered but they are not persuasive.

16. Applicant argues that both TDK and Cohen fail to teach a heterogenous assay.

In response to applicant's arguments, the recitation "heterogeneous immunoassay" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The method of the invention fails to recite a separation step and the remanent magnetization of the bound markers are measured with the presence of the unbound markers.

17. Applicant fails to respond to the double-patenting rejection in the previous office action, therefore, it is still maintained.

Allowable Subject Matter

18. Claims 8, 11-18, 25 and 39 are allowed over the prior arts.

The prior arts do not teach the intrinsic Neelian relaxation times of the ferromagnetic and ferrimagnetic substances that are greater than the measuring time.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is (703) 308-4398. The examiner can normally be reached on Mon-Fri from 7 a.m. to 4 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Pensee T. Do
Patent Examiner
May 7, 2001

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
05/07/01